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Applicants: Peter Zhu et al.

Serial No.: 09/810,889

Art Unit: 1743

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Examiner: L.I. Cross

For : MBTH FOR ALIPHATIC ALDEHYDE MEASUREMENT

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**APPEAL BRIEF**

**I. Real Party in Interest**

This application is assigned to Ethicon, Inc. which is owned by Johnson & Johnson.

## **II. Related Appeals and Interferences**

Although the cases do not claim common priority, co-pending US Application Serial No. 09/810,872 claims similar subject matter and is currently under appeal. Similarly, co-pending US Application Serial No. 10/326,041 has claims to the volumetric measuring techniques employed by this application, and a Notice of Appeal was filed, which was later mooted by the filing of an RCE to allow citation of additional art in the case.

### **III. Status of Claims**

Claims 1 to 13 and 34 to 38 are pending in the application. Claims 1 to 8, 10, 11, 13 and 34 to 38 stand rejected. Claims 14 to 33 have been cancelled. Claims 9 and 12 stand allowed.

#### **IV. Status of Amendments**

No amendments have been filed after issuance of the Final Office Action Mailed April 20, 2005.

## **V. Summary of Claimed Subject Matter**

A method, according to the claimed invention, determines a concentration of an aldehyde in a test sample which is higher, equivalent or lower than a point of interest of the aldehyde wherein the point of interest is an effective concentration of the aldehyde. The method comprises the steps of: (a) reacting the aldehyde in the test sample with an amount of MBTH to produce an azine, wherein said amount is the amount of MBTH that reacts with the aldehyde to the point of interest; (b) producing a first color if the concentration of said aldehyde is higher or equivalent to the point of interest; or (c) oxidizing any unreacted MBTH; (d) reacting the azine and any oxidized MBTH produced in step (c) to produce a second color different from the first color, the second color being indicative that the concentration of said aldehyde is lower than the point of interest; (e) observing an ending color in the test sample comprised of the first color and second colors; and (f) determining whether the effective concentration of aldehyde is present in the test sample based upon the ending color of in the test sample. (see Specification at pg. 6, lines 1 to 34 and FIG. 1)

In one particularly useful aspect of the invention, the aldehyde is glutaraldehyde, which is the active component in many liquid sterilant solutions. (see Specification at pg. 2, lines 14 and 15)

Preferably, the oxidant is mixed with the test sample at the same time as the MBTH reacts with the aldehyde. (see Specification at pg. 2, lines 16 and 17, and pg. 7, lines 9 to 13)

Preferably, the reaction in step (d) produces a formazan to produce the second color. (see Specification at pg. 2, line 5, and pg. 6, lines 9 to 14)

**VI. Grounds of Rejection to be Reviewed on Appeal**

A. Whether the Examiner has established a prima facie case of obviousness in rejecting claims 1 to 8, 10, 11, 13, 34 and 35 under 35 U.S.C. §103 (a) over the Opp US Patent No. 4,471,055, Iannacone et al. US Patent No. 3,645,696 and an alleged admission of prior art in Applicant's specification at page 1, lines 10 to 28?

## VII. Argument

**A. Whether the Examiner has established a prima facie case of obviousness in rejecting claims 1 to 8, 10, 11, 13, 34 and 35 under 35 U.S.C. §103 (a) over the Opp US Patent No. 4,471,055, Iannacone et al. US Patent No. 3,645,696 and an alleged admission of prior art in Applicant's specification at page 1, lines 10 to 28?**

Applicants submit that the Examiner has failed to establish a prima facie case of obviousness in rejecting claims 1 to 8, 10, 11, 13, 34 and 35 under 35 U.S.C. §103 (a) over the Opp US Patent No. 4,471,055, Iannacone et al. US Patent No. 3,645,696 and an alleged admission of prior art in Applicant's specification at page 1, lines 10 to 28. Opp teaches a method for determining the concentration of an aldehyde. However, the method taught by Opp differs significantly from the presently claimed invention. Opp reacts a first reactant with the aldehyde to produce a color. Opp then reacts any remaining aldehyde with a second reactant to produce a second color. In contrast, the present invention provides for reacting not remaining aldehyde with a second reactant but rather any excess of the first reactant, MBTH, that was not consumed during the first reaction. Iannacone et al. provides a system for the detection of ethylene glycol by oxidizing any ethylene glycol present to formaldehyde and then detecting the presence of formaldehyde by reacting it with MBTH to produce a color change in a simple one reactant system.

There is no suggestion for combining Opp and Iannacone et al. Even if combined, it would at best lead one of skill in the art to react MBTH with an aldehyde and then react any remaining aldehyde with a second reactant to produce a second color. However, the present invention rather than reacting in excess of the test aldehyde for the second color reacts the excess of the first reactant. There is no suggestion for such a system. The limitation of using an excess of the second reactant to produce the color change is lacking from the cited references. Accordingly, Applicants respectfully submit that the claimed invention patentably defines over the cited art.

As to claim 5, the prior art cited by the Examiner fails to acknowledge use with Gluteraldehyde and as described on page 1 of Applicants' specification, use of MBTH with



sterilant aldehyde concentrations is difficult due to the need for dilutions, a difficulty overcome by the present invention.

As regards claim 6, the Examiner asserts that Opp teaches addition of both reactants simultaneously. However, Opp does not teach mixing the second reactant to the test sample at the same time as the first reactant is in the process of reacting with the sample. Rather, Opp physically shields the second reactant from mixing with the sample through a delayed release system while the first reacting is occurring.

As regards claim 36, neither reference teaches formation of a formazan.

Applicants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness and request that the rejection be withdrawn and the case moved on to issue.

Respectfully submitted,

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## Claims Appendix

### Claims on Appeal

1. A method of determining a concentration of an aldehyde in a test sample which is higher, equivalent or lower than a point of interest of the aldehyde wherein the point of interest is an effective concentration of the aldehyde comprising the steps of:

(a) reacting the aldehyde in the test sample with an amount of MBTH to produce an azine, wherein said amount is the amount of MBTH that reacts with the aldehyde to the point of interest;

(b) producing a first color if the concentration of said aldehyde is higher or equivalent to the point of interest; or

(c) oxidizing any unreacted MBTH;

(d) reacting the azine and any oxidized MBTH produced in step (c) to produce a second color different from the first color, the second color being indicative that the concentration of said aldehyde is lower than the point of interest;

(e) observing an ending color in the test sample comprised of the first color and second colors; and

(f) determining whether the effective concentration of aldehyde is present in the test sample based upon the ending color of in the test sample.

2. The method of claim 1, wherein the ending color in the test sample is blue, green, yellow or any combination thereof.

3. The method of claim 1, wherein the oxidant is selected from the group consisting of ferric chloride, potassium ferricyanide, lead tetraacetate and periodic acid.

4. The method of claim 1, wherein the oxidant is ferric chloride.

5. The method of claim 1, wherein the aldehyde is glutaraldehyde.

6. The method of claim 1, wherein the oxidant is mixed with the test sample at the same time as the MBTH reacts with the aldehyde.

7. The method of claim 1, wherein the oxidant is added to the test sample after the MBTH reacts with the aldehyde.

8. The method of claim 1 further comprising the step of drawing up a fixed volume of the aldehyde-containing test sample prior to performing step (a).

9. A method of determining a concentration of an aldehyde in a test sample which is higher, equivalent or lower than a point of interest of the aldehyde wherein the point of interest is an effective concentration of the aldehyde comprising the steps of:

(a) drawing up a fixed volume of the aldehyde-containing test sample and loading the fixed volume to a measuring device having a gas or vapor permeable but liquid impermeable membrane;

(b) reacting the aldehyde in the test sample with an amount of MBTH to produce an azine, wherein said amount is the amount of MBTH that reacts with the aldehyde to the point of interest;

(c) producing a first color if the concentration of said aldehyde is higher or equivalent to the point of interest; or

(e) oxidizing any unreacted MBTH;

(f) reacting the azine and any oxidized MBTH produced in step (c) to produce a formazan producing a second color different from the first color, the second color being indicative that the concentration of said aldehyde is lower than the point of interest;

(g) observing an ending color in the test sample comprised of the first color and second colors; and

(h) determining whether the effective concentration of aldehyde is present in the test sample based upon the ending color of in the test sample.

10. The method of claim 1 further comprising the step of drawing up a fixed volume of the aldehyde-containing test sample and loading the fixed volume to a measuring device containing said MBTH.

11. The method of claim 8 further comprising applying the aldehyde in the test sample to an absorbent material.

12. A method of determining a concentration of an aldehyde in a test sample which is higher, equivalent or lower than a point of interest of the aldehyde wherein the point of interest is an effective concentration of the aldehyde comprising the steps of:

(a) drawing up a fixed volume of the aldehyde-containing test sample and applying the aldehyde in the test sample to an absorbent material, wherein the absorbent material is a nylon membrane;

(b) reacting the aldehyde in the test sample with an amount of MBTH to produce an azine, wherein said amount is the amount of MBTH that reacts with the aldehyde to the point of interest;

(c) producing a first color if the concentration of said aldehyde is higher or equivalent to the point of interest; or

(e) oxidizing any unreacted MBTH;

(f) reacting the azine and any oxidized MBTH produced in step (c) to produce a formazan producing a second color different from the first color, the second color being indicative that the concentration of said aldehyde is lower than the point of interest;

(g) observing an ending color in the test sample comprised of the first color and second colors; and

(h) determining whether the effective concentration of aldehyde is present in the test sample based upon the ending color of in the test sample.

13. The method of claim 11, wherein the absorbent material contains MBTH.

34. The method of claim 7, wherein substantially none of the second color is produced when the aldehyde equal to the point of interest.

35. The method of claim 6, wherein less of the second color is produced when the aldehyde is more than or the same as the point of interest than when the aldehyde is less than the point of interest.

36. The method of claim 1 wherein the reaction in step (d) produces a formazan to produce the second color.

37. The method of claim 8 further comprising loading the fixed volume to a measuring device containing said  $\text{FeCl}_3$ .

38. The method of claim 11, wherein the absorbent material contains said  $\text{FeCl}_3$ .

Evidence Appendix

[NONE]

### Related Proceedings Appendix

There are no decisions in the related appeal as of the filing of this brief.